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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,300	11/12/2003	Hosheng Tu	GLAUKO.1C3CP1	5751

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/706,300	TU ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *19-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to an implant for treating glaucoma without a flow restricting means, classified in class 604, subclass 8.

II. Claims 19-45, drawn to an implant for treating glaucoma with a flow restricting means, classified in class 604, subclass 9.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Group I and Group II are directed to related devices. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the shunt without the flow restricting means may use size to control fluid flow, while the shunt with the flow restricting means uses the restricting means to control fluid flow, creating different modes of operation between the devices.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with James Hill on 30 May 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 4, 5, 9, 10, and 12-18 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0119737 to Bene et al.

In the specification and figures, Bene discloses the device as claimed by applicant. With particular regard to claims 1, 2, 4, and 5, Bene discloses an ocular implant with a body 106 that may comprise a drug or bioactive agent impregnated within or as a coating on the housing (see FIG 2, paragraphs 0033, 0046, 0059). The implant comprises an inlet portion 137, outlet portion 135, with opening 136. The device is

configured to relieve intraocular pressure by draining the anterior chamber of the eye of aqueous humor fluid (see FIG 5, paragraph 11). Bene does not specifically disclose that the outlet end deposits drained fluid within Schlemm's canal. However, applicant's recitation that the claimed device is disposed within Schlemm'dscanal of the eye fails to provide any structural difference from the device disclosed by Bene. It is the position of the examiner that the Bene device is capable of being disposed in Schlemm's canal and meets the limitations of the claims.

With regard to claims 9, 10, 12, 13, and 18, Bene discloses that the drug associated with the implant may include a glaucoma treatment (which necessarily lowers the intraocular pressure of the eye, since treatment of glaucoma involves the lowering of intraocular pressure), anti-inflammatory, or anticancer (antiproliferative) agent loaded onto the exterior surface of the device, including the head and foot, wherein the agent may be a polymer layer (which examiner is interpreting as equivalent to the claimed film) containing the bioactive agent (see paragraph 0059, claim 97). The implant and drug layers are constructed to provide drug transmissions over a prolonged period of time (see paragraph 0063).

With regard to claims 14-15, Bene discloses that the shunt body may be constructed of hydrogels (which are biodegradable) and copolymers (see paragraph 0045).

With regard to claims 16-17, Bene discloses that an anti-infective agent may be disposed on a filter 262, which may be located at the outlet end of the device (see FIG

22, paragraphs 0066, 0077). The filter may comprise a pillar structure (see FIGS 38-42), meeting the limitations of the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 3, 6-8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0119737 to Bene et al in view of US 7,033,603 to Nelson.

In the specification and figures, Bene discloses the device substantially as claimed by applicant with the exception of the particular drugs or materials used as bioactive agents in the device. Nelson discloses an implantable hydrogel device that provides drug delivery to various internal locations within a patient. The device disclosed by Nelson may include a growth factor, a gene, TGF-beta, and heparin (see column 7, lines 60-67, column 8, lines 1-22, column 18, lines 50-67, column 17, lines 36-41). It has been held to be within the general skill of a worker in the art to select a known material (or, in this case, drug or bioactive agent) on the basis for its suitability for the intended purpose (in this case, to provide therapeutic treatment) as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the

implant disclosed by Bene with the therapeutic agents disclosed by Nelson in order to provide the desired therapeutic treatment to the patient.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,670,161 Healy et al

i. Biodegradable drug eluting stent

b. US 6,348,042 Warren, Jr.

ii. Bioactive shunt

c. US 7,008,396 Straub

iii. Ophthalmic shunt with drug coating

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
31 May 2006

PATRICIA BIANCO
PRIMARY EXAMINER
6/5/06